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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,692	07/25/2001	Darrell R. Anderson	27693-01009	8484

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SIDLEY AUSTIN LLP  
ATTN: DC PATENT DOCKETING  
1501 K STREET, NW  
WASHINGTON, DC 20005

EXAMINER
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SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/911,692	<b>Applicant(s)</b> ANDERSON ET AL.	
	<b>Examiner</b> Ron Schwadron, Ph.D.	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 70-78 and 98-107 is/are pending in the application.
- 4a) Of the above claim(s) 76-78, 100-102 and 105-107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 70-75, 98, 99, 103 and 104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                 | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

1. Claims 100-102,105-107 are withdrawn from consideration as being drawn to nonelected inventions for the reasons elaborated in paragraph 2 of the previous Office action. Said previous election was made without traverse in the paper filed 11/14/2003. Applicants request for rejoinder is noted.

2. Claims 70-75,98,99,103,104 are under consideration.

3. The amendment filed 12/13/06 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. The amended abstract constitutes new matter for essentially the same reasons that claim 70 constitutes new matter as per below.

Applicant is required to cancel the new matter in the reply to this Office Action.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 70-75,98,99,103,104 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A)There is no support in the specification as originally filed for the host cell of claim 70/72. The claims encompass host cells that express nucleic acids encoding membrane bound anti-CD20 antibody, yet there is no disclosure of such cells in the specification as originally filed. The claims encompass host cells that express the nucleic acid recited in the claims in the absence of additional regulatory nucleic acid sequences required for secretion of the antibody yet such cells are not disclosed in the specification. The claims encompass host cells that only contain the specific nucleic acid recited in the claims wherein such host cells are not disclosed in the specification as originally filed.

Regarding applicants comments about the specification, page 24, said page discloses that the host cell is transfected with a plasmid, wherein the claimed host cell does not require presence of plasmid associated nucleic acids as per disclosed in the specification. In addition, based on the teachings of the specification (such as page 42), it appears that the plasmid would require specific sequences required for expression and secretion of the chimeric antiCD20 antibody. There is no support in the specification as originally filed for the scope of the claimed invention (aka the claimed inventions constitute new matter).

Regarding applicants comments, the host cells CHO and SP2/O as per disclosed in page 24 of the specification are cells that are transfected with a plasmid, not cells that contain the nucleic acid recited in the claims in the absence of a plasmid (see page 24, lines 20-21, "Transfection of the plasmid into the host cell can be accomplished by any technique available to those in the art.". Based on the specification, page 24, it appears the host cell refers to a cell that will be transfected with a plasmid that contains the sequence recited in the claims and wherein the plasmid directs expression of the antibody. The claims encompass host cells that express the antibody recited in the claims in the absence of a transfected plasma wherein such a cell is not disclosed in the specification. Similarly, the specification, page 19, lines 22-29; continued on next page refers to host cells transfected with a plasmid. In addition, said section refers to antibody which is purified from the host cells transfected with a plasmid. It does not refer to transmembrane bound antibody. Regarding the deposited cells to which applicant refers, TCAE 8 is described in the specification as a vector, which is then transfected into a host cell (aka CHO or SP2/O, see page 43). Regarding applicants comment about 08/147,696, cloning vectors are not host cells as per use of the term in the specification. Regarding applicants comments, the claims encompass host cells which only contain the nucleic acid recited in the claims wherein such cells are not disclosed in the specification.

Regarding applicants comment as to what "host cell" means, based on the specification, page 24, the "host cell" is a cell that is later transfected with an expression plasmid. In addition, regarding applicants comments as to how one of ordinary skill in the art would interpret the aforementioned term, the MPEP section 716.01(c) states:

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## **II. ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE**

The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

The MPEP section 2163.02 states:

### **2163.02 Standard for Determining Compliance With the Written Description Requirement**

The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession

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of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. This conclusion will result in the rejection of the claims affected under 35 U.S.C. 112, first paragraph - description requirement, or denial of the benefit of the filing date of a previously filed application, as appropriate. See MPEP § 2163 for examination guidelines pertaining to the written description requirement.

As per stated above, the test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter."

The specification as originally filed does not reasonably convey to the artisan that the inventor had possession at that time of the later claimed subject matter for the reasons elaborated above.

B) There is no support in the specification as originally filed for the host cells of claims 98/103. As per stated above, the specification discloses a host cell transfected with a plasmid containing the nucleic acid recited in the claims wherein said cell has the functional attributes recited in the claim, but does not disclose host cells absent a transfected plasmid with the functional attributes recited in the claims.

There is no support in the specification as originally filed for the claimed inventions (aka the claimed inventions constitute new matter).

6. No claim is allowed.


7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the

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examiner's supervisor, Christina Chan, can be reached on 517 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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